In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-0559V
UNPUBLISHED

WANDA RODGERS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 9, 2021 Special Processing Unit (SPU); Entitlement; Table Injury; Ruling on the Record Without Hearing; Influenza (Flu) Vaccine; Tetanus, Diphtheria, acellular Pertussis ("Tdap") Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Isaiah Richard Kalinowski, Maglio Christopher & Toale, PA, Washington, DC, for Petitioner.

Mallori Browne Openchowski, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On April 18, 2018, Wanda Rodgers filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,[2] (the "Vaccine Act"). Petitioner alleged that she suffered shoulder injuries related to vaccine administration ("SIRVAs") in both right and left shoulders which meet the criteria for Table

[1] Because this unpublished Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

SIRVAs and were casually related to the influenza ("flu") and tetanus, diphtheria, acellular pertussis ("Tdap") vaccines she received on September 13, 2016. Petition at ¶¶ 3, 14, 17. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

Based on the record as a whole and for the reasons discussed below, I find Petitioner suffered two SIRVAs - one in each shoulder - which satisfy the Table SIRVA definition. Furthermore, I find by preponderant evidence that Petitioner is entitled to compensation under the Vaccine Act.

I. Relevant Procedural History

From April through July 2018, Ms. Rodgers filed the affidavit and medical records required under the Vaccine Act. Exhibits 1-5, ECF Nos. 4, 11; *see* Section 11(c). During the remainder of 2018 and 2019, the parties discussed a factual issue regarding the site of vaccination,[3] and Petitioner filed additional documentation and updated medical records. Exhibits 6-8, ECF Nos. 21, 28; Status Reports, ECF Nos. 19, 24, 29; Status Conference held May 23, 2019. On March 11, 2020, I issued a fact ruling, finding the two vaccines Petitioner received had been administered one in each arm, as she alleged. ECF No. 36.

During March through August 2020, the parties attempted to reach an informal settlement in the case. *See, e.g.,* Status Report, ECF No. 44. On August 26, 2020, they informed me they had reached an impasse in their settlement discussions. Status Report, ECF No. 45. On October 30, 2020, Respondent filed his Rule 4(c) Report, setting out his objections to compensation. ECF No. 47.

On January 6, 2021, I held a call with the parties to discuss entitlement. *See* Scheduling Order, issued Jan. 6, 2021, ECF No. 48. After providing my initial impressions regarding the arguments made by Respondent in his Rule 4(c) Report, I outlined a briefing schedule. I informed Petitioner's counsel that, if I was unable to resolve entitlement in favor of Petitioner, I would be transferring the case out of SPU. *Id.* The parties completed their briefing on March 24, 2021. ECF Nos. 49-52, 55-56.

[3] The vaccine record indicates that Petitioner received both the flu and Tdap vaccines in her left deltoid. Exhibit 1 at 65.

II. Relevant Factual History

The medical records show Petitioner suffered prior conditions, including brachial venous occlusion,[4] which caused pain down her arms (Exhibit 1 at 102), and cervical radiculopathy (*id.* at 61). *See id.* at 8-150. At the September 13, 2016 visit to her primary care provider ("PCP") when she received the flu and Tdap vaccinations alleged as causal, Petitioner sought a surgical referral for the removal of lipomas[5] on her right arm and knee. Exhibit 1 at 62, 65. Indicating they had existed for approximately five years, she described the lipoma on her knee as increasing in size and the lipoma on her right arm as "hurting when working out." *Id.* at 62.

Less than a month later, on October 4, 2016, Petitioner called the clinic of her PCP (Dr. Kevin Katzen), where she received the vaccinations in question, complaining of soreness in both arms after receiving the flu and Tdap vaccines during the prior month. Exhibit 8 at 2. Petitioner first spoke to an individual who reported Petitioner "still cannot bring her arm over her head without pain since her last vaccines 3 weeks ago." *Id.* The call was routed to another individual at the clinic. After speaking to Petitioner, this individual noted Petitioner "c/o[6] soreness on both arms from when she got the Flu and Tdap vaccine on 9-13-16" and "can't sleep cause no matter which side she turns, her arms hurt." Exhibit 8 at 2. Petitioner's PCP indicated that he wished to see Petitioner. *Id.*

At her appointment that same day, Petitioner repeated her complaint of pain in both arms after receiving the flu and Tdap vaccinations in September 2016.[7] Exhibit 1 at 2 (indicating "c/o both arms are very painful"). When examining Petitioner, Dr. Katzen observed no warmth or swelling but bilateral tautness and pain. *Id.* at 3 (indicating "B/l[8] deltoid taut and painful").

Petitioner called her PCP three more times during that month, on October 7, 13, and 27, 2016. Exhibit 8 at 8-12. The notes from the October 27, 2016 call indicate

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[4] Brachial venous occlusion is the blockage of blood flow through the veins in the upper arm. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 244, 1311, 2046 (32nd ed. 2012).

[5] A lipoma is "a benign, soft, rubbery, encapsulated tumor of adipose tissue, usually composed of mature fat cells." DORLAND'S at 1063.

[6] The abbreviation "c/o" can stand for the phrase "complains of". MEDICAL ABBREVIATIONS at 141 (16th ed. 2020).

[7] The exact date in this record is listed as September 19, 2016. Exhibit 1 at 2. However, as noted earlier in this Ruling, the correct date of vaccination is September 13, 2016. Exhibit 1 at 65.

[8] It appears this abbreviation stands for "bilateral". MEDICAL ABBREVIATIONS at 89 (indicating the abbreviation "BL" can mean bilateral).

Petitioner wished "to speak with staff about her injection site[9]" and that she had come "in for her flu and Tdap shot and then discovered pain in her shoulders after her injections were given." Exhibit 8 at 8. During these calls, Petitioner requested additional and stronger antibiotics to rid her of the cellulitis she was experiencing and referenced a cortisone injection she claims to have received at the October 4, 2016 urgent care appointment with her PCP. *Id.* at 8, 11. Although there is no reference to a cortisone injection in the record from the October 4, 2016 visit (*see* Exhibit 1 at 2-7), in her affidavit, Petitioner claims her PCP "agreed to provide steroid injections at no charge in order to appease [her]." Exhibit 5 at ¶ 9.

When visiting her surgeon, Dr. Julio Rivera, on November 8, 2016, Petitioner indicated she wished to postpone surgery on her right medial arm and right medial knee masses because she was having soreness from immunizations. Exhibit 2 at 12-13.

Petitioner called her PCP again on November 10, 2016. Exhibit 8 at 7. On that call, Petitioner "stated her arms/shoulder pain is about the same, not better." *Id.* She described the pain as worse when she was still and lying down but better as long as she is moving during the day. *Id.* She indicated she was unaware that Keflex[10] had been prescribed for her and thus, had not yet picked it up. Exhibit 8 at 7.

At her initial visit with Dr. Carmen Campbell at Southwest Arthritis Research Group on February 1, 2017, between four to five months post-vaccination, Petitioner indicated that, after receiving the flu and Tdap vaccines in October or November, "she developed swelling in her lateral shoulders (near injection sites) and pain in her shoulders." Exhibit 3 at 7. She further indicated that she "was diagnosed with cellulitis and treated with bactrim." *Id.* In addition to pain in her shoulder joints, Petitioner reported pain in her thumbs which radiated up her arms, pain in her wrists, and ten to fifteen minutes of stiffness in the mornings. To treat these symptoms, Petitioner indicated that she takes Advil pm at night which "partially alleviates her symptoms," uses a gel in the morning, but has not attended physical therapy ("PT"). *Id.*

Dr. Campbell indicated that she suspected Petitioner's thumb and wrist pain was caused by underlying osteoarthritis, adding that she would evaluate that premise after reviewing x-rays of these areas. Exhibit 3 at 9. Regarding Petitioner's shoulder pain, Dr. Campbell opined that its etiology was "unclear." *Id.* She listed differential causes of rotator

[9] Although this entry uses the singular site, instead of sites, it also references to two vaccination. Exhibit 8 at 8. Thus, I previously found that the use of the singular site was a simple mistake. Fact Ruling at 5 n.6, ECF No. 36.

[10] Keflex is a cephalosporin antibiotic used to treat a wide variety of bacterial infections. *See* https://www.webmd.com/drugs/2/drug-6859/keflex-oral/details (last visited Aug. 31, 2021).

cuff tendinopathy, bursitis, and osteoarthritis, noting that Petitioner's presentation would be atypical for rheumatoid arthritis. She prescribed x-rays and indicated she would consider an MRI of Petitioner's right shoulder if needed. *Id.*

On March 10, 2017, Petitioner underwent an MRI of her right shoulder which revealed partial tearing of the supraspinatus and subscapularis tendons, degenerative tearing of the superior labrum, mild AC joint arthrosis, and mild subacromial subdeltoid bursitis. Exhibit 4 at 31.

On April 4, 2017, Petitioner returned to the rheumatologist, Dr. Campbell. Exhibit 3 at 10. Noting that Petitioner "continues to experience bilateral shoulder pain," Dr. Campbell addressed the "multiple structural abnormalities" shown on Petitioner's March 10, 2017 right shoulder MRI. *Id.* Upon examination, she observed limitations in Petitioner's range of motion, noted as greater for her right shoulder than left. *Id.* at 11. Petitioner also reported intermittent stiffness bilaterally in her thighs. *Id.* at 10. Dr. Campbell referred Petitioner to an orthopedist for her shoulder pain and structural abnormalities on the MRI and prescribed PT for Petitioner's bilateral thigh/hip tightness. *Id.* at 12.

When Petitioner was first seen by an orthopedist on April 5, 2017, she indicated "[s]he had vaccines in both shoulders back in September . . . [and] started having pain immediately after that." Exhibit 4 at 6. She described her pain as constant, immediate, and present for six months, adding that it was worse on her right side than left. She indicated her pain increased with activity, work, and lifting anything over 25 pounds and decreased with hot showers. She reported that her rheumatologist had prescribed antibiotics which did not help, that she had undergone an MRI, and that she had no prior injections or surgeries on either shoulder. *Id.*

The orthopedist, Dr. Brody Flanagin, observed Petitioner was experiencing "tenderness over her coracoid process bilaterally, . . . bicipital groove, and rotator interval, . . . essential[ly] normal active and passive ROM in all planes bilaterally, . . . [and] [p]ain but no significant weakness with resisted rotator cuff strength testing." Exhibit 4 at 7. Regarding the cause of Petitioner's shoulder pain, Dr Flanagin opined that Petitioner's "[s]ymptoms seem consistent with SIRVA." *Id.* at 8. He injected both shoulders with lidocaine and Kenalog. *Id.* at 7-8.

At a follow-up appointment with Dr. Flanagin on May 24, 2017, Petitioner reported significant pain relief after the injections she received in early April. Exhibit 4 at 4. Although her pain had returned, again worse on the right side, she indicated that she still felt "about

40% better." *Id.* She acknowledged that her shoulder pain had worsened after she began working out and swimming. *Id.*

Upon examination, Dr. Flanagan observed the same areas of tenderness previously seen on the right shoulder but not left, "full elevation and rotation in all planes, [and] [m]ild pain without weakness on resisted rotator cuff strength training bilaterally." Exhibit 4 at 5. Because the April injections were administered approximately six weeks earlier, Dr. Flanagan recommended that he hold off on another set of injections and that Petitioner attend PT for both shoulders. *Id.*

It appears Petitioner did not pursue PT in 2017. Instead, she returned to Dr. Flanagan on July 5, 2017 for another set of injections, reporting a few months of relief after the April injections. Exhibit 4 at 2. Dr. Flanagan again injected both shoulders with the same solution of lidocaine and Kenalog. He discussed a left shoulder MRI or right shoulder surgery as logical next steps. *Id.* at 3.

On July 11, 2017, Petitioner called Dr. Flanagan's office, complaining of a lack of pain relief. Exhibit 6 at 16. She was advised to wait a few days and informed that an MRI of her left shoulder would be ordered if needed. *Id.* at 17. After responding that she did not want to pursue a left shoulder MRI due to financial issues, Petitioner asked if she should try ice and heat for her soreness and pain – she was advised to do so. *Id.* at 18.

Petitioner did not require additional treatment until February 2019. During this time, she contacted Dr. Flanagan's office only once in October 2017, to request paperwork exempting her from receiving the flu vaccine. Exhibit 6 at 15.

When seen again by Dr. Flanagan on February 6, 2019, Petitioner exhibited no tenderness, or issues with her ROM. Exhibit 6 at 11-12. Dr. Flanagan noted that she "[s]eems to have more clicking and popping in the shoulder than real pain." *Id.* at 12. He recommended PT for rotator cuff strengthening. *Id.*

At her initial PT appointment on February 20, 2019, Petitioner reported that both her shoulders became swollen after receiving the flu and Tdap vaccinations. Exhibit 7 at 13, 17. This history is repeated in the record from each subsequent session. *Id.* at 20, 23, 26, 29, 32, 35, 38, 41, 47, 50, 53. On the intake form, Petitioner reported pain at a level of two out of ten only in her right shoulder. *Id.* at 10. After attending twelve PT sessions, Petitioner was discharged on April 10, 2019. In these PT records, it was noted that, although she "kept reporting that her bicipital groove was painful," Petitioner's current pain was in her glenohumeral joint, following the head of her humerus. *Id.* at 55.

III. Legal Standard for Entitlement

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1). Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[11] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, *or* an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

[11] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

If, however, petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, she must prove that the administered vaccine caused injury to receive Program compensation. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A). The Federal Circuit has held that to establish an off-Table injury, petitioner must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Federal Circuit has indicated that a petitioner "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface,* 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). It added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in a three-pronged test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the

> vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.* Circumstantial evidence may be considered, and close calls regarding causation must be resolved in favor of the petitioner. *Id.* at 1280.

IV. Summary of the Parties' Arguments

In his Rule 4(c) Report, filed on October 30, 2020, Respondent argues that Petitioner has not established that she suffered bilateral Table SIRVA Injuries because she has failed to show that the onset of her pain occurred within 48 hours, or that her "pain was limited to the arm in which the vaccine was given." Rule 4(c) Report at 6; *see* 42 C.F.R. § 100.3(c)(10)(ii)-(iii) (two QAI criteria in question).

In her motion for a ruling on the record as it currently stands, filed in February 2021, Petitioner argues in response that she has provided sufficient proof to establish that she suffered both left and right shoulder injuries meeting the Table definition for SIRVA or which, in the alternative, were caused by the vaccines she received. Motion for Findings of Fact and Conclusions of Law Regarding Entitlement to Compensation ("Motion") at 7-21, ECF No. 51. To further support her arguments, she filed medical literature and a supplemental declaration. Exhibits 12-31, ECF Nos. 49-50, 52.

Respondent contests Petitioner's assertions. Respondent's Response to Pet. Motion ("Opp.") at 1, ECF No. 55. Incorporating the arguments set forth in his Rule 4(c) Report, Respondent asserts that Petitioner had failed to satisfy the two QAI criteria previously discussed, as well as a third criteria mentioned for the first time in the response. *Id.* at 1-2. Specifically, Respondent argues that Petitioner has failed to establish that she had no history of prior shoulder pain which would explain her current condition. *Id.* at 2; *see* 42 C.F.R. § 100.3(c)(10)(i). It appears Respondent believes he addressed this additional QAI criteria in the Rule 4(c) Report, as he cites to pages in his Rule 4(c) Report and provides no further argument on the issue. Opp. at 2.[12]

[12] In her reply, Petitioner responded to a Respondent criticism of a characterization made by Petitioner in her supplemental declaration which is not germane to the issue of entitlement. Reply Memorandum in Support of Pet. Motion, ECF No. 56; *see* Opp. at 2; Exhibit 31 at 10 (Petitioner's declaration).

V. Finding of Fact: Onset

As the Federal Circuit has stated, contemporaneous medical records are deemed to "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). In this case, Petitioner's contemporaneously created medical records contain preponderant evidence supporting a factual finding that the onset of Petitioner's bilateral shoulder pain occurred within 48 hours of vaccination - an issue directly bearing on entitlement in this case.

Respondent argues that the onset descriptions provided by Petitioner in the contemporaneously created medical records are too imprecise to establish the Table onset, such as the description of pain "within minutes" found in Petitioner's affidavit. Rule 4(c) Report at 6 (comparing an entry created three weeks post-vaccination reporting pain since vaccination at Exhibit 8 at 2 with an entry in Petitioner's affidavit at Exhibit 5 at ¶ 2, stating her pain began within minutes of vaccination). However, I find this to be a specious distinction.

As early as three weeks post-vaccination, Petitioner complained of "soreness on both arms *from when* she got the Flu and Tdap vaccine [sic]." Exhibit 8 at 2 (emphasis added). Further, she described an inability to raise her arms overhead "without pain *since* her last vaccines 3 weeks ago.*" Id.* (emphasis added). During the remainder of October, she was seen by her PCP once and called him on three other occasions complaining of her continued pain. Exhibit 1 at 2-7; Exhibit 8 at 8-12. When seen by an orthopedist, on April 4, 2017, Petitioner reported that she "started having pain *immediately after*" her September vaccinations. Exhibit 4 at 6 (emphasis added). Coupled with the lack of any entries describing a delayed onset, such proof is sufficient to establish that Petitioner's bilateral shoulder pain began immediately after she received the flu and Tdap vaccines.

VI. Entitlement

As previously stated in Section III, a petitioner suffering a shoulder injury following receipt of the flu vaccine is entitled to compensation under the Vaccine Act if she can establish by preponderant evidence that her injury satisfies the definition for a Table SIRVA or was caused-in-fact by the flu vaccine she received. Section 11(c)(1)(C). In her Petition, Ms. Rodgers advances both types of claim.

A. Table Injury: SIRVA

As stated in the previous section, I find there is sufficient evidence to establish that the onset of Petitioner's bilateral shoulder pain was immediate, and thus, within 48 hours

as required by the Vaccine Injury Table and accompanying SIRVA QAI. 42 C.F.R. § 100.3(a)(XIV)(B); 42 C.F.R. § 100.3(c)(10)(ii). Additionally, Respondent does not dispute that Petitioner's alleged SIRVAs meet the fourth QAI criteria, and there is a scarcity of evidence showing an alternative cause for Petitioner's bilateral shoulder pain. 42 C.F.R. § 100.3(c)(10)(iv). Thus, I find that Petitioner has satisfied this fourth QAI requirement as well and will limit my discussion to the remaining two QAI criteria.

1. Prior Shoulder Pain

The first QAI criteria requires that a petitioner have "[n]o history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that *would* explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection." 42 C.F.R. § 100.3(c)(10)(i) (emphasis added).

Although Respondent disputes that Petitioner has satisfied this criteria, he advances no specific argument and fails to identify the prior pain, inflammation or dysfunction upon which he relies. Thus, I have considered the only two possibilities: 1) the right arm pain caused by the venous occlusion Petitioner suffered in 2012; and 2) the right arm pain which occurred when working out and was caused by the lipoma existing on Petitioner's medial arm at the time of vaccination.

In her motion, Petitioner addresses only the first possibility. Underscoring the nature, timing, and resolution of the venous occlusion she suffered in 2012, Petitioner argues that the "thrombotic condition . . . could not have caused the injuries to [her] shoulder in 2016 and the years that follow." Motion at 10.

I credit Petitioner's argument regarding the differing types of injuries involved. It is unlikely that the venous occlusion Petitioner experienced would explain the bilateral shoulder pain she later suffered.

Similarly, due to its location, the lipoma which existed on Petitioner's right arm at the time of vaccination would not explain her post-vaccination right *shoulder* pain. As I discussed when determining the site of Petitioner's vaccinations,[13] the lipoma was located

[13] I determined that, located in Petitioner's right medial arm, the lipoma would not have prevented the vaccine administrator from following the usual procedure of injecting two vaccine in both arms. Fact Ruling at 7.

on Petitioner's right medial arm,[14] causing right *arm* pain which is clearly distinguishable from the right *shoulder* pain she suffered post-vaccination.

I find that neither the prior right arm pain caused by venous occlusion Petitioner suffered in 2012 nor the right arm pain when working out caused by the lipoma existing at the time of vaccination would qualify as pain, inflammation or dysfunction which would explain Petitioner's post-vaccination. Thus, I find Petitioner had satisfied this QAI criteria.

2. Location of Petitioner's Pain

The last QAI criteria to be satisfied involves the location of Petitioner's pain and limited range of motion. To qualify for a Table SIRVA, a petitioner's pain and reduced range of motion must be limited to the shoulder in which the vaccine was administered. 42 C.F.R. § 100.3(c)(10)(iii).

When addressing this QAI criteria, Respondent emphasizes the lack of uniformity regarding the symptoms Petitioner experienced in her right and left shoulders, specifically mentioning that the symptoms Petitioner experienced in her left shoulder were milder and emphasizing the fact that a left shoulder MRI was never performed. Rule 4(c) Report at 6-7. Respondent also references the history Petitioner provided to the rheumatologist in which she also complained of pain in her wrists and thumbs which radiated up her arms, and the statement by Petitioner's rheumatologist, Dr. Campbell, indicating that he "suspected a 'multi-factorial' process was causing [P]etitioner's symptoms." *Id.* at 7 (citing Exhibit 3 at 9).

Citing language in the introductory paragraph of the SIRVA QAI, Petitioner maintains that this requirement regarding location applies only to symptoms experienced at the onset or manifestation of a SIRVA. Motion at 11. She distinguishes the symptoms Petitioner later reported, such as the pain Petitioner experienced in her wrists and fingers, from "her initial complaints of symptoms which were clearly limited to her shoulders, which is where her symptoms manifested." *Id.* at 11-12. Petitioner criticizes Respondent's arguments as an overly narrow interpretation of the criteria, characterizing them as requiring Petitioner to be free from all other pain. *Id.* at 12.

I do not accept Petitioner's characterization regarding the timing of this requirement - that it applies only to the initial symptoms a petitioner suffers. Indeed, the requirements for a Table SIRVA mandate only that a petitioner's *pain* occur within 48

[14] Medial means "pertaining to the middle; closer to the median plane or the midline of a body or structure." DORLAND'S at 1118. Thus, it appears Petitioner's lipoma was located lower on her arm, possibly on the inner part of her elbow.

hours or vaccination[15] - not that they also immediately experience reductions in range of motion, which often lag after the initial injury by weeks or months. It would be illogical for a requirement which applied to a petitioner's decreased range of motion, as well as pain, to be limited in the manner Petitioner asserts.

However, I find the portion of Petitioner's argument regarding *unrelated* areas of pain persuasive, and agree that this QAI criteria does not prevent a petitioner with simultaneous areas of pain due to unrelated conditions from also meeting the Table SIRVA definition. In this case, the medical records clearly establish that Petitioner suffered from pain in numerous areas caused by multiple unrelated conditions, both prior to and following vaccination. And Dr. Campbell's suspicions that Petitioner's bilateral shoulder and thumb/wrist pain were multi-factorial supports this premise. Exhibit 3 at 9. Dr. Campbell opined that Petitioner's finger and wrist pain was likely due to osteoarthritis, but proposed other possibilities for the source of her bilateral shoulder pain - including rotator cuff tendinopathy and bursitis. Regarding the possibility that the bilateral shoulder pain was due to rheumatoid arthritis, Dr. Campbell, a rheumatologist, opined that Petitioner's "[p]resentation would be atypical for RA." *Id*. The one entry cited by Respondent, regarding pain in Petitioner's wrists and fingers, is not sufficient to prevent her from satisfying this criteria.[16]

Respondent's argument regarding the lack of uniformity in the severity of Petitioner's symptoms is similarly unpersuasive. In proposing the Table addition of SIRVA, Respondent discussed the scientific evidence regarding the means by which this injury is caused – and in so doing specifically referenced the article also filed by Petitioner in this case. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45136-37 (July 29, 2015); S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Exhibit 12, ECF No. 49-2 ("Atanasoff"). As noted in Atanasoff, many of the patients studied may have had prior conditions such as rotator cuff tears which became symptomatic following the improper vaccine injection. Atanasoff at 8051. Indeed, the right shoulder MRI Petitioner underwent in early March 2017 revealed significant degenerative changes, which may account for the greater severity of symptoms Petitioner experienced in her right shoulder. Exhibit 3 at 41. Although this assumption cannot be confirmed due to the lack of a left shoulder MRI, I do not need to know the basis for the difference in severity. Given that Petitioner's shoulder conditions prior to vaccination are likely to differ, proof of mirror-image severity in the rare case of a bilateral SIRVA after two vaccinations

[15] *See Portee v. Sec'y of Health & Human Servs.,* No. 16-1552V, 2018 WL 5284599 (Fed. Cl. Spec. Mstr. Sept. 14, 2018) for further discussion regarding this issue.

[16] Of course, distinguishing SIRVA-related pain from pain attributable to a different injury bears heavily on damages – and Petitioner in this case must make sure to draw such distinctions when seeking damages.

cannot be the standard, as Respondent seems to propose. Regarding the more relevant issue, the type of symptoms suffered, the descriptions Petitioner provided throughout the medical records of her symptoms were identical.

The record in this case shows that in multiple entries, especially those created closer in time to vaccination, Petitioner consistently reported pain and difficulties with movement which was confined to both shoulders. *E.g.,* Exhibit 1 at 4. Petitioner has satisfied this remaining QAI requirement. She has established, by preponderant evidence, that both of her shoulder injuries meet the Table SIRVA definition.

B. Causation-in-Fact: SIRVA

Although a detailed discussion of Petitioner's causation-in-fact claim is not required, it is worth noting that the record also contains evidence likely sufficient to satisfy the three-pronged *Althen* test for both shoulder injuries. *See Althen,* 418 F.3d at 1278. I have previously taken judicial notice of the fact that Respondent has added SIRVA after receipt of an intramuscularly administered seasonal influenza vaccine to the Vaccine Injury Table as evidence of the causal link between vaccine and injury needed to satisfy the first *Althen* prong. *Lesher v. Sec'y of Health & Human Servs.,* No. 17-1076V, 2020 WL 4522381, at *11 (Fed. Cl. Spec. Mstr. July 2, 2020) (citing *Doe 21 v. Sec'y of Health & Human Servs.,* 88 Fed. Cl. 178, 193 (2009), *rev'd on other grounds*, 527 Fed. Appx. 875 (Fed. Cir. 2013)). Regarding the second *Althen* prong, Petitioner's orthopedist opined Petitioner's bilateral shoulder pain seemed consistent with SIRVA. Exhibit 4 at 8. In establishing that a vaccine "did cause" an injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Capizzano v. Sec'y of Health & Human Servs.,* 440 F.3d 1317, 1326 (Fed. Cir. 2006). Finally, given that Petitioner has satisfied the onset required for a Table SIRVA, she would, no doubt, have no difficulty establishing the medically acceptable time frame needed for actual causation.

C. Additional Requirements for Entitlement

Even though she has established that she suffered Table SIRVAs in both shoulder following her September 13, 2016 vaccinations, Petitioner must satisfy the additional requirements in Section 11(c) regarding the vaccinations received, the duration and severity of petitioner's injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D).

The vaccine record shows the flu and Tdap vaccines were administered to Petitioner on September 13, 2016, at her PCP's clinic in Texas. Exhibit 1 at 65; *see* Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)

(requiring administration within the United States or its territories). Although the vaccine record indicated both vaccines were administered in Petitioner's left deltoid, I previously found there was preponderant evidence showing the vaccines were administered one in each arm as Petitioner alleges. Fact Ruling, issued Mar. 11, 2020, ECF No. 36. Additionally, there is no evidence that Petitioner has collected a civil award for her injury. *See* Section 11(c)(1)(E) (lack of prior civil award).

Regarding the six-month severity requirement, the medical records show Petitioner complained of bilateral shoulder pain, with only short periods of relief due to steroid injections, from vaccination until early July 2017. Exhibit 6 at 16-18. When first seen by an orthopedist on April 5, 2017, prior to her first steroid injections, Petitioner reported pain which was as constant, immediate, and present for more than six months. Exhibit 4 at 6. In order to meet this requirement, Petitioner must establish that her symptoms occurred beyond March 13, 2017. Despite reporting a greater level of pain in her right shoulder, Petitioner clearly indicated she was suffering from bilateral shoulder pain. *E.g., id.* Thus, I find that the medical records show that more than six months after vaccination, Petitioner continued to suffer the residual effects of both SIRVAs. *See* Section 11(c)(1)(D)(i) (statutory six-month requirement). Petitioner has satisfied all requirements for entitlement under the Vaccine Act.

D. Severity and Duration of Petitioner's Pain and Suffering

As I previously noted in this ruling, Petitioner suffered pain due to conditions unrelated to her SIRVAs both prior to and following vaccination. At the time of vaccination, she was suffering from right knee and arm pain attributed to lipomas in these areas. Exhibit 1 at 62. Furthermore, in early 2017, it was noted that Petitioner suffered from pain in her wrists and fingers, most likely due to osteoarthritis. Exhibit 3 at 7. Although these unrelated symptoms and conditions do not prevent Petitioner from establishing that she is entitled to compensation, they are relevant when determining the appropriate amount of compensation to be awarded.

Furthermore, it appears Petitioner obtained significant relief from the steroid injections she received in early April and July 2017. For example, at her second orthopedic appointment in late May 2017, Petitioner characterized her overall condition as "feeling about 40% better." Exhibit 4 at 4. Upon examination, the orthopedist observed that Petitioner had *full* range of motion and *mild* pain bilaterally. *Id.* at 5. In contrast, prior to this first set of steroid injections, Petitioner described her pain as moderate to severe. *Id.* at 6. Although Petitioner reported continued pain in July 2017, following the second set of steroid injections administered in early July 2017, she must have ultimately obtained relief because she did not return for treatment until almost 19 months later in

early February 2019. *See* Exhibit 4 at 10 (regarding July 5, 2017 injections); Exhibit 6 at 16-18 (calls later in July 2017).

At her first PT session in late February 2019, Petitioner complained of only *right* shoulder pain at a level of *two* out of ten. Exhibit 7 at 10. She attributed her symptoms to the vaccines she received in late 2016 (*id.* at 13), but the record as it currently stands does not support that assertion. When he examined Petitioner in early February 2019, her orthopedist, Dr. Flanagan, observed *full* range of motion and no tenderness. Exhibit 6 at 11-12. He indicated Petitioner "[s]eems to have more clicking and popping in the shoulder than real pain." *Id.* at 12. At her PT discharge on April 10, 2019, it was noted that Petitioner reported pain in her bicipital groove as she experienced in 2016-17, but when asked to identify the location of her pain, pointed to her glenohumeral joint and head of her humerus. Exhibit 7 at 55.

Given that Petitioner suffered from bilateral SIRVAs in 2016, the compensation awarded for the pain and suffering she experienced in 2016-17 is likely to be greater than for a petitioner who suffered a SIRVA in only one shoulder. However, as Petitioner herself acknowledges (Motion at 12), she also suffered unrelated pain during this time. Additionally, the pain Petitioner suffered in her left shoulder was less severe than what she experienced in her right shoulder, and she obtained significant relief from the steroid injections she received in 2017. The parties should consider all these factors when attempting to informally resolve the issue of damages in this case.

VII. Conclusion

Having reviewed the affidavits, medical records, and briefing in this case, I find that Petitioner has provided preponderant evidence to establish that she suffered Table SIRVAs in both her right and left shoulders. Petitioner is therefore entitled to compensation under the Vaccine Act. A damages order will be issued setting the next deadline in this case.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master